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Charles Henry Horn

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EXAMINER

HENKEL, DANIELLE B

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,679	Applicant(s) HORN, CHARLES HENRY	
	Examiner DANIELLE HENKEL	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 6/15/2009 has been entered and fully considered.
2. Claims 56-78 are pending, previously pending claims 33-55 have been cancelled by Applicant's amendment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 56-64, and 71-78 rejected under 35 U.S.C. 103(a) as being unpatentable over KERTZ (WO 90/15527).
 - a. With respect to claim 56, KERTZ teaches a method comprising disposing an inoculum in an inoculation chamber (inner container) (Page 29, Paragraph 3) and disposing a growth medium for the inoculum in an anaerobic proliferation

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chamber (Page 29, Paragraph 3 and Page 15, Paragraph 2) which is separated from the inoculation chamber by an openable separator (Page 11, Paragraph 2- Page 12, Paragraph 1), storing the inoculum and uninoculated growth medium separated (Page 29, Paragraph 3), opening the separator to inoculate the growth medium (Page 30, Paragraph 1), allowing the cells, tissue cultures, and or microorganisms to proliferate under anaerobic conditions in the proliferation chamber to form a proliferated culture (Page 30, Paragraph 2- Page 31, Paragraph 1), and dispensing the proliferated culture from the proliferation chamber (Page 31, Paragraph 1). KERTZ teaches the inoculation chamber is anaerobic (not gas permeable, closed from environment) (Page 8, Paragraph 1 and Page 20, Paragraph 2), and the steps of inoculating (Page 11, Paragraph 2 – Page 12, Paragraph 3 and Page 4, Paragraph 3), opening (Page 11, Paragraph 2 – Page 12, Paragraph 3 and Page 4, Paragraph 3), and proliferation occur anaerobically (Page 15, Paragraph 2). KERTZ does not explicitly disclose the steps of disposing occur anaerobically. However, KERTZ does teach that materials can be disposed in the chambers after they are sealed through the use of a tube (Page 10, Paragraph 3) and that the culture can be preformed anaerobically (Page 15, Paragraph 2). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to perform all steps of preparing an anaerobic culture vessel anaerobically.

b. With respect to claim 57, KERTZ discloses an inoculation chamber (inner container) containing an inoculum (Page 29, Paragraph 3), and an openable

separator (material of inner container) that separates the proliferation chamber from the inoculation chamber, wherein opening of the separator allows inoculation of the growth medium with the inoculum (Page 11, Paragraph 2- Page 12, Paragraph 1). As the inoculum chamber is sterile and closed from contaminants (Page 20, Paragraph 2), the inoculum will be stable and viable beyond those in conventional culture containers (Page 31, Paragraph 3).

c. With respect to claim 58, KERTZ teaches the separator (material of inner container) and the inside of the proliferation chamber are sterile prior to disposing the inoculum and medium (Page 20, Paragraph 2).

d. With respect to claim 59, KERTZ teaches controlling proliferation conditions of the inoculated growth medium (Page 42, Paragraph 5 - Page 43, Paragraph 1).

e. With respect to claim 60, KERTZ teaches a unitary (Figure 1), disposable (Page 16, Paragraph 2), and portable (Page 9, Paragraph 2) apparatus comprising an anaerobic proliferation chamber (cellule) (Page 15, Paragraph 2) containing a growth medium (Page 35, Paragraph 3 - Page 36, Paragraph 1), and inoculation chamber (inner container) containing an inoculum (Page 29, Paragraph 3), and a means for separating the proliferation and inoculation chambers (openable separator), the separating means being openable to connect the insides of the chambers to each other to inoculate the growth medium with the inoculum (Page 11, Paragraph 2- Page 12, Paragraph 1) wherein the inoculum and growth medium are stored and transported separated

from each other in the apparatus until such time as a proliferated culture is to be applied (Page 29, Paragraph 3 – Page 30, Paragraph 2 and Page 33, Paragraph 3-Page 34, Paragraph 1), whereupon the growth medium is inoculated and proliferation allowed to take place, whereafter the proliferated culture is dispensed from the apparatus (Page 30, Paragraph 2 – Page 31, Paragraph 2). As the inoculum chamber is sterile and closed from contaminants (Page 20, Paragraph 2), the inoculum will be stable and viable beyond those in conventional culture containers (Page 31, Paragraph 3).

f. With respect to claim 61, KERTZ teaches storing the inoculum and uninoculated growth medium separated (Page 29, Paragraph 3), opening the separator to inoculate the growth medium (Page 30, Paragraph 1), allowing the cells, tissue cultures, and or microorganisms to proliferate under anaerobic conditions in the proliferation chamber to form a proliferated culture (Page 30, Paragraph 2- Page 31, Paragraph 1), and dispensing the proliferated culture from the proliferation chamber (Page 31, Paragraph 1).

g. With respect to claim 62, KERTZ teaches the separator (material of inner container) and the inside of the proliferation chamber are sterile (Page 20, Paragraph 2).

h. With respect to claim 63, KERTZ teaches the inoculation chamber is anaerobic (not gas permeable, closed from environment) (Page 8, Paragraph 1 and Page 20, Paragraph 2).

- i. With respect to claim 64, KERTZ teaches the apparatus is totally enclosed (Page 7, Paragraph 2) and hermetically sealed (heat sealed and anaerobic chamber) (Page 8, Paragraph 2, and Page 15, Paragraph 2).
- j. With respect to claim 71, KERTZ teaches the inoculation chamber is flexible and compressible after the separator has been opened (Page 11, Paragraph 2 – Page 12, Paragraph 1).
- k. With respect to claim 72, KERTZ teaches an urging function (pressing) that urges the inoculum into the proliferation chamber after the separator has been opened (Page 11, Paragraph 2 - Page 12, Paragraph 1).
- l. With respect to claim 73, KERTZ teaches a pressure difference between chambers (pressure on inner container) causes the inoculum to flow into the proliferation chamber after the separator has been opened (Page 11, Paragraph 2).
- m. With respect to claim 74, KERTZ teaches a port (tube) for connecting to a dosing or application means (Page 10, Paragraph 3).
- n. With respect to claim 75, KERTZ teaches the pressure difference is created during the anaerobic cultivation of the cells, tissue culture, or microorganisms in the inoculation chamber (Page 11, Paragraph 2- Page 12, Paragraph 1).
- o. With respect to claim 76, KERTZ teaches the proliferation chamber comprises a flexible (expandable) bag-type container (Page 8, Paragraph 2 and Figure 4).

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p. With respect to claim 77, KERTZ does not explicitly disclose the proliferation chamber comprises a carboy-type container. However, it would be a matter of obvious design choice of one having ordinary skill in the art at the time that the invention was made, since a flexible bag and a carboy are both well known culture containers.

q. With respect to claim 78, KERTZ discloses the claimed invention except for providing additional proliferation chambers connectable to the other chambers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide multiple chambers, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

6. Claims 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over KERTZ (WO 90/15527) as applied to claims 56-64 and 71-78 above, in view of BITTINGS (US 4358539).

a. With respect to claim 65, KERTZ does not explicitly disclose the chambers are connected by a passage. However, BITTINGS teaches a subculture device for transferring inoculum in which a passage (neck of culture bottle) is provided between a culture chamber (culture media well) and inoculum container (culture bottle) comprising the separator (septum) (Column 2, line 55-Column 3, line 32, Figure 1). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the culture apparatus of KERTZ to include the

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inoculum transfer including a passage comprising the separator as taught by BITTINGS because it allows for a minimum of handling, thus reducing contamination as well as eliminates the need for a separate transfer syringe and needle (Column 3, lines 40-55).

b. With respect to claim 66, BITTINGS teaches the separator comprises a septum because it is standard on a culture bottle containing inoculum (Column 1, lines 36-44).

c. With respect to claim 67, BITTINGS teaches the opener comprises a spike (needle) for piercing the septum because it is common for transferring inoculum to media through the septum of a standard culture bottle (Column 1, lines 36-44).

d. With respect to claim 68, BITTINGS teaches the inoculation chamber comprises a mouth (neck of bottle) connected to one end of the passage (Column 3, lines 19-32). BITTINGS does not explicitly disclose the inoculation chamber comprises a vial-type container, however, BITTINGS does disclose the chamber is a standard culture bottle. It would be obvious to one of ordinary skill in the art at the time of the invention to use a vial-type container as the inoculation chamber because the use of vial-type containers for holding inoculum where well known in the art.

e. With respect to claim 69, BITTINGS teaches the septum covers the mouth (Column 3, lines 19-32).

f. With respect to claim 70, BITTINGS teaches the spike is mounted in the passage and directed at the septum (Figure 1), and wherein the mouth of the

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inoculation chamber is connected to the passage by an advancer (a person) that advances the inoculation chamber towards the spike thereby allowing the spike to pierce the septum (Column 3, lines 19-32).

Response to Arguments

7. Applicant's arguments filed 6/15/2009 have been fully considered but they are not persuasive. Absent specific arguments detailing how the art of record does not render obvious the newly amended claims, the Examiner maintains that the art of record renders the current claims obvious for the reasons presented above. Any new grounds of rejection presented were due to amendments made in the claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1797

/William H. Beisner/
Primary Examiner, Art Unit 1797